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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,851	05/29/2007	William Brown	101260-1P US	1341

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ASTRA ZENECA PHARMACEUTICALS LP  
GLOBAL INTELLECTUAL PROPERTY  
1800 CONCORD PIKE  
WILMINGTON, DE 19850-5437

EXAMINER
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LEESER, ERICH A

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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08/19/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/596,851	<b>Applicant(s)</b> BROWN ET AL.	
	<b>Examiner</b> Erich A. Leeser	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 5-20-08.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8, 9 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-14 is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is in response to Applicant's Remarks and Amended Claims dated May 20, 2008, in which Applicant cancelled claims 10 and 15. Claims 1-5, 8-9, and 11-14 are currently pending and under examination.

#### ***Claim Rejections - 35 USC § 112***

Examiner previously rejected claims 10 and 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because while enabling for the treatment of pain, the specification does not enable the instant compounds to treat anxiety or functional gastrointestinal disorders or enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Based on Applicant's cancellation of these claims, Examiner withdraws this rejection.

#### ***Claim Rejections 35 U.S.C. § 103***

Examiner previously rejected claims 1-5 and 8 under 35 U.S.C. § 103(a) as being unpatentable over Brown, et al., U.S. Patent No. 7,253,173. As Applicant correctly points out, the reference is not prior art for reasons of record. There is more than sufficient support in Swedish application No. 0400027-9 to perfect Applicant's claim of foreign priority. As such, Examiner withdraws this rejection.

#### ***Claim Objections***

Examiner previously objected to claim 9 as being dependent upon rejected independent claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

### ***New Grounds of Rejection***

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 6, and 7 of Brown, et al., U.S. Patent No. 7,253,173. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims is also embraced in Brown, et al., U.S. Patent No. 7,253,173. The claims of the reference and the instant claims are obvious variants of one another because claim 1 of the reference recites R<sup>1</sup> is hydrogen and the

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instant claims recite R<sup>1</sup> is C1-6alkyl; dependent claim 5 has a compound wherein R<sup>1</sup> is methyl-- see compound 20. One of ordinary skill in the art would be motivated to produce a diarylmethyl piperazine derivative compound given the prior art reference. It is sufficient if a reference compound is so closely related to the claimed compound that a chemist would find the difference an obvious variation. Thus, claims are rejected where the difference is primarily one which exists between a secondary amine and a tertiary amine. See *Ex parte Bluestone*, 135 USPQ 199 (1961).

This obviousness-type double patenting rejection is non-provisional because the conflicting claims have in fact been patented.

### ***Claim Objections***

Claim 9 is objected to as being dependent upon rejected independent claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

### ***Allowable Subject Matter***

Claims 11-14 are patentable over Andrus Brown, et al., U.S. Patent No. 7,253,173. The reference discloses processes of making 4(phenyl-piperazinyl-methyl)benzamide derivatives which do not read on or suggest the process claims of the instant application. The difference between the process claims of the patent and the instant process claims of the application is based on the definition of the reactants: in the reference the reactants are either alkylcarbamate or heteroaryl-CHO, whereas the instant claims require the reactants to be either halogen or non-heteroaryl-CHO. Therefore, the claims are free of prior art.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

**/James O. Wilson/**

**Supervisory Patent Examiner, Art Unit 1624**

**Erich A. Leeser**

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